

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0040
CUSTOMER NUMBER: 689

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Huntingdon Life Sciences Inc
P.O. Box 2360
East Millstone, NJ 08875

Telephone: (732)-873-2550

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	1	1075	44	30	1149
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	400	4	20	424
9. Non-human Primates	6	367	111	28	506
10. Sheep					
11. Pigs	0	63	1	0	64
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)(c)

Type or Print)

DATE SIGNED

11/13/07

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A) Explanation of Category E Studies

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify pre-clinical testing requirements necessary for approval of new drugs. Specific regulations and/or guidelines include the following:

- FDA Part VI, Volume 61, No. 166, Single Dose Acute Toxicity Testing for Pharmaceuticals, August 1996.
- International Conference on Harmonization (ICH) Harmonized Tripartite Guideline (S5A): Detection of Toxicity to Reproduction for Medicinal Products, III/3387/93.
- International Conference on Harmonization (ICH) S5B: Maintenance of the ICH Guideline on Toxicity to Male Fertility An Addendum to the ICH Tripartite Guideline on Detection of Toxicity to Reproduction for Medicinal Products
- International Conference on Harmonization (ICH) S3A: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies.
- M3 (R1): Maintenance of the ICH Guideline on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals, 1997. Amended November 2000 (Maintenance Process), and M3 (R2) Final Concept Paper, September 2006.
- OECD Guideline No. 409, 9/21/98 Repeated Dose 90-day Oral Toxicity Study in Non-rodents.
- FDA Redbook 2000 (Updated July 2007), Toxicological Principles for the Safety Assessment of Food Ingredients, Short Term Toxicity with Non-rodents.
- International Conference on Harmonization (ICH) S4: Single Dose Toxicity Tests
- ICH Guidance for Industry, S7A Safety Pharmacology Studies for Human Pharmaceuticals, II. GUIDANCE, D. Dose Levels or Concentrations of Test Substance (2.4), In Vivo Studies (2.4.1)
- 21 CFR 312.22, Investigational New Drugs/Biologics

Species	Number of Category E Animals	Description
Dogs	1	Animals were exposed to test article for one year. One dog exhibited clinical signs consistent with those of a brief idiopathic ictal episode.
Dogs	4	Animals were exposed to test article for approximately one month. Test article effects were evident in 4 animals. Dose administration was discontinued in these 4 dogs.
Dogs	2	Animals were exposed to test article once. Test article effects were evident in 2 dogs. Both dogs were humanely euthanized.
Dogs	2	Animals were exposed to test compound for approximately 5 days. Brief test article effects were evident in 2 dogs.

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Species	Number of Category E Animals	Description
Dogs	7	Animals were exposed to test compound for approximately 14 days. Test article effects were evident in 7 dogs. Due to the fact that the test article was a mu-agonist, additional analgesia was contraindicated. Test article doses were lowered in animals exhibiting marked effects.
Dogs	4	Animals were exposed to test compound for 1 day. Test article effects were evident in 4 dogs. Dose administration was discontinued in affected dogs.
Dogs	3	Animals were exposed to test article for approximately 14 days. Test article effects were evident in 3 dogs. All 3 dogs received palliative treatments for test article effects.
Dogs	4	Animals were exposed to test article for approximately 14 days. Test article effects were evident in 4 dogs. Animals received palliative treatment and were eventually humanely euthanized.
Dogs	3	Animals were exposed to test article for approximately 28 days. Test article effects were evident in 3 dogs. Dosing was suspended and affected animals were humanely euthanized.
Rabbit	2	Animals were exposed to test compound via for approximately twelve days. Test article effects were evident in 2 animals. Dosing was discontinued for one rabbit, and the second was humanely euthanized.
Rabbit	6	Animals were exposed to test compound for approximately two weeks. Test article effects were evident in 6 animals. Affected animals were humanely euthanized.
Rabbit	1	Animals were exposed to test compound for approximately two weeks. Adverse effects that could not be directly attributed to test article administration were evident in 1 animal. Consequently, this animal was humanely euthanized.
Rabbit	11	Animals were exposed to test compound for approximately two weeks. Test article effects were evident in eleven animals. These animals were humanely euthanized.
Monkey	4	Animals were exposed to test compound for approximately two weeks. Test article effects were evident in four animals. These four animals were humanely euthanized.
Monkey	9	Animals were exposed to test compound for approximately 7 days. Test article effects were evident in 9 animals. Of these 9 animals, 8 were humanely euthanized prior to study completion.

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Species	Number of Category E Animals	Description
Monkey	1	Animals were exposed to test compound for approximately two weeks. One animal was euthanized due to test article effects.
Monkey	1	Animals were exposed to test compound for approximately 5 doses. Test article effects were evident in one animal that received palliative treatment and was eventually euthanized.
Monkey	3	Animals were exposed to test compound for approximately 28 days. Test article effects were evident in three animals that were initially treated and then euthanized.
Monkey	1	Animals were exposed to test compound as a single dose. Test article effects of brief duration were evident in one animal.
Monkey	4	Animals were exposed to test compound for approximately 5 days. Test article effects were evident in four animals, three of which were treated, and one of which was humanely euthanized.
Monkey	5	Animals were exposed to test compound for approximately 28 days. Test article effects were evident in five animals. Due to the fact that the test article was an analgesic, additional analgesia was contraindicated. Animals exhibiting marked effects received palliative treatment and clinical support.

B) Summary of IACUC-approved exceptions to the Standards and Regulations:

- 27 dogs were exempted from the exercise requirement for 14 days during recovery from a surgical procedure.
- 4 dogs were exempted from the exercise requirement for 28 days for individual telemetric data collection.
- 4 dogs were exempted from the exercise requirement for 6 days, and 1 dog for 2 days, for individual telemetric data collection.
- 4 dogs were exempted from the exercise requirement for 6 days and 1 dog for 2 days, during individual telemetric data collection.
- 4 dogs were exempted from the exercise requirement for 3 days during individual telemetric data collection.